DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 24, 2014

DePuy Spine, Incorporated
Ms. Kirsten Lehmuller
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K140927
Trade/Device Name: Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 15, 2014
Received: September 16, 2014

Dear Ms. Lehmuller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140927

Device Name
Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems

Indications for Use *(Describe)*
The Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using tracking arrays provided by the navigation manufacturer. These procedures include but are not limited to spinal fusion. These devices can be pre-calibrated and/or manually calibrated with Brainlab Navigation system, where other navigation systems require manual calibration.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

A. Submitter Information

Manufacturer:	Medos International Sárl Chemin-Blanc 38 2400 Le Locle, Switzerland
Submitter:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02767
Contact Person:	Kirsten Lehmuller 325 Paramount Drive Raynham, MA 02767
Telephone number:	508-828-3291
Fax number:	508-828-3797
Email:	klehmull@its.jnj.com

B. Date Prepared April 10, 2014

C. Device Name

Trade/Proprietary Name:	Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems
Common/Usual Name:	Stereotaxic Instrument
Classification Name:	Class II, per 21 CFR §882.4560 OLO; Orthopedic

D. Predicate Device Name

Trade name:	EXPEDIUM and VIPER Navigated Instruments (K120867) Synthes Navigable Pedicle Preparation Instruments (K122211) Brainlab VectorVision Fluoro 3D System (K070106) Medtronic StealthStation (K050438)

E. Device Description

The Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems are manual surgical instruments which are designed to interface with previously cleared surgical navigation systems. The instruments in this system are manually calibrated to previously cleared surgical navigation systems using manufacturers' instructions. These instruments are intended to be used in spine applications to perform general manual functions within the orthopedic surgical environment. The Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems are intended for use with the EXPEDIUM 5.5 Spine System and VIPER and VIPER 2 MIS Spine Systems components.

F. Intended Use

The Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems are intended to assist the surgeon in precisely locating anatomical structures in either open, minimally invasive, or percutaneous procedures. These are indicated for use in surgical spinal procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or a vertebrae can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy using tracking arrays provided by the navigation manufacturer. These procedures include but are not limited to spinal fusion. These devices can be pre-calibrated and/or manually calibrated with Brainlab Navigation system, where other navigation systems require manual calibration.

G. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The design features, materials, and indications for use of the subject Universal Navigation Instruments are substantially equivalent to the predicate devices identified.

H. Materials

The Universal Navigation Instruments are manufactured from stainless steel: 17-4PH, custom 455, custom 465, 18-8, 316, 316L, 420, 302, aluminum: 6061-T6, plastic: RADEL R5500, and titanium alloy.

I. Performance Data

DePuy Spine performed verification and validation activities for the Universal Navigation Instruments for EXPEDIUM and VIPER MIS Spine Systems. The Universal Navigation Instruments for EXPEDIUM and VIPER MIS Spine Systems were tested in a controlled

bench top environment in order to compare the overall accuracy to predicate instruments. Testing with third party navigation software was completed to validate calibration with the use of the universal adaptor and the universal clamp attachment. All the subject instruments were successfully calibrated using the third party software according to the instructions provided by the software manufacturer.

In order to assess the rigidity of the connection between the universal clamps and arrays and the subject devices, DePuy Spine performed verification testing in a controlled bench-top environment. For each third-party manufacturer, all combinations of connections were evaluated under expected loading conditions and compared to predicate instruments. All connections performed equal to or better than the predicate instrument.

J. Conclusion

The Universal Navigation Instruments for EXPEDIUM® and VIPER® MIS Spine Systems intended use, principles of operation, and technological characteristics are substantially equivalent to those predicates identified.